

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As noted in the Office Action Summary, claims 1-24 are pending. Claims 1, 6, and 11 are amended herein. Claims 25-31 are new claims added herein. Basis for the amendments to the claims and new claims may be found in the claims and specification as-filed, especially at claims 3, 11 and 13-15.

Claims 2, 4-5, 7-8, and 17-24 are canceled herein. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

Claim Objections

Claims 17-24 stand objected to as purportedly duplicative of claims 5-16. To this end, Applicants note that claim 17 (from which claims 18-24 depend either directly or indirectly) depends from claim 2 whereas claim 5 (from which claims 6-16 depend directly or indirectly) depends from claim 3 which further defines the amide compound. Applicants request that this objection be withdrawn.

Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-24 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly lacking written description support for the claims as directed to any process for preparing any amide-containing solution using any microorganism fungus body containing any nitrile hydratase of any amino acid or structure. Applicants traverse.

The test for sufficiency of descriptive support in an application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at the time the invention was filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). Additionally, "[i]t is not necessary that the claimed subject matter be described in *ipsis verbis* to satisfy" the requirement. *Heymes v. Takaya*, 6 U.S.P.Q.2d 1448, 1452 (Bd. Pat. App. & Int. 1988). Nor does the statute require a working example to meet the requirements of § 112, first paragraph. *Id.*

To that end, Applicants submit that the specification adequately supports the claims under the written description requirement. The present claims, as submitted herein, are not directed to any amide-containing solution using any microorganism fungus body containing any nitrile hydratase of any amino acid or structure. Rather, the claims do not all require any type of microorganism. In fact, claim 1 does not make any reference to any microorganism. In the presently claimed invention, it is the recitation that the amide compound-containing solution is placed in contact with activated carbon under acidic conditions which is the subject matter of independent claim 1, not the source of the amide compound-containing solution.

Thus, the claims, as directed to a process for purifying an amide compound comprising containing solution in contact with activated carbon under acidic conditions and separating activated carbon, wherein the amide compound has an unsaturated bond and is produced by contacting a nitrile compound with a microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body, are supported by the specification such that the

skilled artisan would understand the inventors had possession of the invention at the time of filing. Applicants request that this rejection be withdrawn.

Rejections Under 35 U.S.C. § 112, second paragraph

Claims 1-24 stand rejected for purportedly omitting essential steps. Independent claim 1 has been amended herein to recite the further steps of separating activated carbon, wherein the amide compound has an unsaturated bond and is produced by contacting a nitrile compound with a microorganism fungus body containing nitrile hydratase or a processed product of the microorganism fungus body.

Claims 1-24 stand rejected for the recitation of "characterized by making". This phrase has been removed from the claims, and thus this rejection is obviated.

Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-4 stand rejected under 35 U.S.C. § 103 over Oriel (WO 99/55719) in view of Chen (J. Bio Chem. 1967, 242:173-81). Applicants traverse.

For a *prima facie* case of obviousness, the following three requirements must be met. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine the reference with another reference. Second, the proposed modification must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. Third, the prior art

reference must teach or suggest all the limitations of the claims. The teachings or suggestions, as well as the expectation of success, must come from the prior art and not from applicant's disclosure. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991); and *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991).

Applicants respectfully submit that the cited references, alone or in combination, do not meet the requirements for a *prima facie* case of obviousness. There is not motivation provided by the skilled artisan to modify Oriel with Chen to arrive at the presently claimed invention.

Chen is directed to a method of removing lipid impurities from a serum albumin by charcoal treatment under acidic condition. Serum albumin is bounded by various lipid impurities. A serum albumin is a protein. Lipid impurities consist of long-chain fatty acids or its derivative (ester) and an analog. Under acidic conditions, fatty acids bound to serum albumin are dissociated, and the dissociated fatty acids are adsorbed by charcoal. (see Chen, page 174, the right column, "Effect of pH"). Therefore, Chen teaches a process step for removing lipid impurities such as fatty acid from protein such as serum albumin. However, Chen fails to disclose any process step for removing protein.

In contrast, in the present case, an amide compound is produced by directly hydrating a nitrile compound by using a nitrile hydratase, and the amide compound-containing solution contains protein originated from the nitrile hydratase (microorganisms). In the present claims, protein is removed from the amide compound-containing solution by acid-charcoal treatment.

Further, it is well known in the art, and stated in the present specification, that an amide compound having an unsaturated bond is likely to cause polymerization reaction in an acidic region to make the compound unstable. In order to avoid such phenomenon, it is important that the solution containing an amide compound is maintained neutral (see present specification, page 3, lines 11-18.)

Therefore, charcoal treatment of unsaturated amide containing solution under acidic condition is not obvious to one of ordinary skill in the art, and so there is no motivation to modify the methods of Oriel with the methods of Chen.

Claims 5, 7, 9, 17, and 19-24 stand rejected under 35 U.S.C. § 103 over Oriel in view of Chen, as further applied to Rezende et al. (*J. Gen. Appl. Microbiol.* 1999, 45:185-192). Applicants traverse.

The deficiencies of Oriel as combined with Chen are discussed above. Rezende merely discloses yeast strains isolated, and then tested for their ability to use acetonitrole as the nitrogen source. It does not remedy the deficiencies of Oriel and Chen.

Claims 6, 8, 10-16, and 18, stand rejected under 35 U.S.C. § 103 over Ito et al. (U.S. Patent No. 5,910,432) in view of Rezende and Chen. Applicants traverse.

As amended herein, claim 6 now depends on claim 1. Claim 8 and claim 18 are canceled herein. Claims 10-16 depend, directly or indirectly, on claim 6.

Ito is directed to *Pseudonocardia thermophila*-derived nitrile hydratase, and a method for changing its amino acid sequence and base sequence without changing the functions of the nitrile hydratase. Chen and Rezende are discussed above. As noted, Chen fails to disclose any process step for removing protein.

In contrast, in the present claims are directed to an amide compound, produced by directly hydrating a nitrile compound by using a nitrile hydratase, and the amide compound-containing solution contains protein originated from the nitrile hydratase (microorganisms). In the present claims, protein is removed from the amide compound-containing solution by acid-charcoal treatment.

In light of the above remarks, Applicants request that the rejections under 35 U.S.C. § 103 be withdrawn.

CONCLUSION

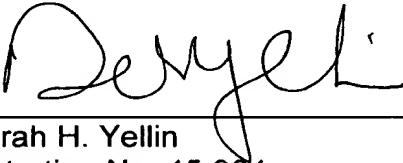
It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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